

# **EXHIBIT 9**

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# Mallinckrodt Controlled Substance Suspicious Order Monitoring Program

Introductory Training for Field Sales  
June 5, 2008

## Mallinckrodt Suspicious Order Monitoring Introductory Training Goals

- Suspicious Order Monitoring Team Membership
- Regulatory background
- Overview of draft procedure
- Field Sales future participation in program



# Mallinckrodt Suspicious Order Monitoring Procedure Team

- JoAnne Levy, V-P Corporate Logistics
- John Adams, Sales Director
- Bill Ratliff, Security Director
- Kimberly France, Business Development Director
- Karen Harper, DEA Compliance Manager
- Michael Phenev, Logistics Manager
- Jim Rausch, Customer Service Manager
- Cathy Stewart, Customer Service Manager
- Susan Marlatt, Credit/Collections Manager

## Team Advisors:

Jerry Moss, V-P Sales

Jason Jones, V-P Sales

Jeff Burd, Marketing Director

Bob Lesnak, Sales & Marketing Director

Eileen Spaulding, Hobart



# DEA Policy on Suspicious Orders

## *DEA Regulation 21 CFR 1301.74*

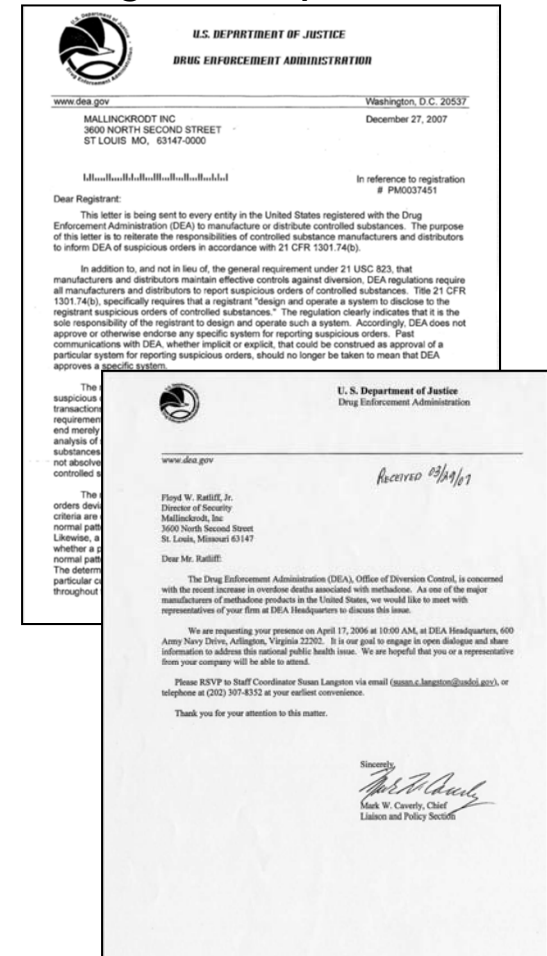
- Requires registrants to **design** and **operate** a suspicious order identification system
- Requires that registrants **report** suspicious orders to DEA when discovered through monitoring
- Registrant is reminded that their responsibility does not end merely with the filing of suspicious order report
- DEA does not approve or otherwise endorse any specific program for reporting suspicious orders
- ***Registrant must conduct an independent analysis of suspicious orders prior to completing a sale to determine whether the controlled substances are likely to be diverted.***



# Consequences of Monitoring Failure

*DEA reiterates responsibilities in light of the growing Rx drug abuse problem*

- Failure to maintain effective controls against diversion is inconsistent with the public interest and may result in the revocation of the registrant's DEA Certificate of Registration.
- Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency



***DEA can immediately suspend or revoke registration for violations of the Controlled Substances Act and regulations.***



# Recent DEA Actions Involving Distributors

***DEA suspends licenses of distributors for not maintaininig effective controls against diversion of controlled substances***

## **Amerisource Bergen**

- Orlando, FL (4/07)

## **Cardinal**

- Auburn, WA (12/07)
- Lakeland, FL (12/07)
- Swedesboro, NJ (12/07)
- Stafford, TX (2/08) under investigation-order to show cause
- Company estimates \$30 million loss due to enforcement actions.

## **McKesson**

- McKesson Corporation Agrees to Pay More than \$13 Million to settle claims that it failed to report suspicious sales of prescription medications





## Bulk Narcotics Compounding Pharmacy Case Study

- DEA was investigating customer for their distribution of human growth hormone and observed Mallinckrodt Nal product at pharmacy
- DEA contacted Mallinckrodt and suggested we review our relationship with the customer and future order shipment
- DEA commented on the presence of Ketamine/Fentanyl in the illicit market
- Customer had placed an order for 4 x 25 grams Fentanyl using Research Registration
- Customer was informed by Mallinckrodt that their pending Fentanyl order had been put on hold
- Customer decreased their order
- Customer cancelled their order



## Revised Controlled Substance Suspicious Order Monitoring Procedure Highlights

- Field Sales completes customer checklist
- Credit performs Dun & Bradstreet and other information checks
- CSRs follow existing procedure on verifying customer DEA registration, quota, DEA 222 Form
- Order entry system flags “peculiar” orders of unusual size, frequency based upon algorithm
- Algorithm is customized by customer category, class of trade
- Customer accounts or customer orders that appear “peculiar” based on customer checklist results, credit checks, CSR interaction, order entry system flag are referred to Security Director and DEA Compliance Manager
- Security Director and DEA Compliance Manager consult with business rep regarding ship or no ship decision
- Security Director and DEA Compliance Manager report suspicious orders to DEA



## Revised Controlled Substance Suspicious Order Customer Checklist

- To be completed by Field Sales
- Know your customer is the goal
- Description of neighborhood (high crime area, etc.)
- Requires on-site visit, inside and out
- Physical description of facility or photos
- Includes a list of indicators (watch outs) that require further review by Security Director

